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10/672,053

09/26/2003

Arnold R. Leiboff

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05/13/2008

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EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

05/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/672,053 | Applicant(s) LEIBOFF, ARNOLD R. | |
| | Examiner Ginger T. Chapman | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 40-42, 44, 66-68, 78 and 80-95 is/are pending in the application.
4a) Of the above claim(s) 2-4, 9, 80 and 82-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. In view of the Appeal Brief filed on September 4, 2007, PROSECUTION IS HEREBY REOPENED. New Grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761.

Status of the claims:

Claims 18-39, 43, 45-65, 69-77 and 79 are cancelled; claims 1-17, 40-42, 44, 66-68, 78 and 80-95 are pending in the application, claims 2-4, 9, 80 and 82-84 are withdrawn from consideration as being directed to nonelected inventions, claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 are examined on the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8, 13-17, 40, 42, 44, 66-68, 81, and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al (US 5,443,445).

5. With respect to claim 78, as best depicted in Figures 2 and 4, Peters teaches a tube for attaching to a bowel, comprising a tubular body (11) having a front end adapted to be inserted into a bowel.

6. Peters disclosed the claimed device except for a sewing ring. Peters teaches straps (25) for securing the device to the bowel (c. 3, ll. 45-60). It would have been an obvious matter of design choice to use straps instead of a sewing ring since both perform the substantially identical function of securing the device to the bowel and Applicant has not disclosed the sewing ring solves any stated problem and it appears the device would perform equally well with the straps

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disclosed in Peters, since Peters states, at c. 4, ll. 1-7, that other securing elements such as ligatures could be used instead of the straps; ligatures are sutures that are sewn during surgery, thus the prior art teaches that both strapping and sewing work equally well to prevent the tube from slipping out of the bowel, substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Siebentritt* 152 USPQ 618 (CCPA 1967).

7. With respect to claims 1, 16, 17, 68, 81-90, 94 and 95, Peters discloses the claimed invention except for the circumferential sewing ring; Peters teaches circumferential straps for securing the device to a bowel (fig. 3). It would have been an obvious matter design choice to use straps instead of a sewing ring since both perform the substantially identical function of securing the device to the bowel and Applicant has not disclosed the sewing ring solves any stated problem and it appears the device would work equally well with the straps disclosed in Peters since Peters states, at c. 4, ll. 1-7, that other securing elements such as ligatures could be used instead of the straps; ligatures are sutures that are sewn during surgery, thus the prior art teaches that both strapping and sewing work equally well to prevent the tube from slipping out of the bowel, substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Siebentritt* 152 USPQ 618 (CCPA 1967).

8. With respect to claims 2, 3, 4, 40, 66 and 89, as best depicted in Figures 1, 2 4, and 6, Peters teaches sidearm (12) extending form a side of the body (10) having a proximal end (11) adapted to be inserted into a bowel and the side arm (12) being adapted to mate with an outflow tube (3) at a distal end.

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9. With respect to claims 5-8, 67 and 91-93, as best depicted in Figure 6, Peters teaches sheath (c. 3, ll. 19-20) which covers the tube (3). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sheath in the claimed location since Peters states, at c. 3, ll. 19-22, that the benefit of forming the device with a sheath is that the sheath provides a cover that envelopes the a tube thereby allowing the drain tube to be gripped without exposing the user of the device to bowel effluent and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

10. With respect to claims 13-15, 42 and 44, Peters discloses the claimed invention except for a plurality of triangular lips. As best depicted in Figures 1, 2 4 and 6, Peters teaches collars (24) and recesses (25) for securing the device within the bowel. It would have been an obvious matter of design choice to use lips instead of collars since Applicant has not disclosed the lips solve any stated problem and it appears that the invention would work equally well with the collars disclosed in Peters since Peters states, at c. 4, ll. 20-25, that this ensures the bowel is held securely to the device.

11. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al (US 5,443,445) in view of Kaplan et al (US 3,908,660).

12. With respect to claim 11, Peters discloses the claimed invention except for the body is transparent. Kaplan, at c. 1, l. 60, teaches the ability of the body of the device to be transparent, thus providing motivation for such. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body of Peters transparent as taught by Kaplan since Kaplan states at c. 3, ll. 33-36, that the advantage of

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providing a transparent body is that it allows a laser beam to be used to form a slit in the colon wall.

13. With respect to claim 12, Peters discloses the claimed invention except for at least one thread for mating with a screw cap. As best depicted in Figure 1, Kaplan teaches at least one thread (54) for mating with a screw cap (52). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device of Peters with a thread and screw cap as taught by Kaplan since Kaplan states, at c. 2, ll. 15-17, that the advantage to forming the device with this design is that the threads hold the components together.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,

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7, 12, and 25-26 of copending Application No. 11/189,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims contain all the limitations of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16.

Response to Arguments

17. Applicant's arguments with respect to claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
5/6/08

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761